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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/755,667 | 01/13/2004 | Hiroshi Maeda | Q79414 | 9625 |
| 65565 | 7590 | 05/30/2007 | | |
| SUGHRUE-265550 | | | EXAMINER | |
| 2100 PENNSYLVANIA AVE. NW | | | WHITE, EVERETT NMN | |
| WASHINGTON, DC 20037-3213 | | | | |
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| | | | 1623 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/755,667

Applicant(s)

MAEDA ET AL.

Examiner

Everett White

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,21-24 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,21-24 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 14, 2007 has been entered.
2. The amendment filed May 14, 2007 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) Claims 2, 7-21 and 25-36 have been canceled;
 - (B) New Claim 37 has been added;
 - (C) Comments regarding Office Action have been provided drawn to:
 - (I) 103(a) rejection, which has been maintained for the reasons of record.
3. Claims 1, 3-6, 22-24 and 37 are pending in the case.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1, 3-6, 22-24 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makuuchi et al (US Patent No. 6,117,815) in view of De Ambrosi et al (US Patent No. 4,987,222) for the reasons disclosed on pages 3-5 of the Office Action filed May 30, 2006.

Applicant's arguments filed September 29, 2006 have been fully considered but they are not persuasive. Applicants argue against the rejection by arguing that the present invention is not to simply obtain a saccharide having a lowered molecular weight by irradiating a polysaccharide having a high molecular weight with an electron beam but also to obtain a saccharide having a desired molecular weight by suitably calculating the electron beam to be used according to the equation in claim 1. This argument is not persuasive since mathematical formulas are not given patent protection. The Makuuchi et al and De Ambrosi et al patents establish irradiating a polysaccharide having a high molecular weight with an electron beam. It is within the skill of an artisans to use techniques to controlled the electron beam irradiating a polysaccharide in order to obtained a saccharide having a desired molecular weight that does not require the use of the claimed mathematical equation. Furthermore, the molecular weight of the saccharides Applicants are obtaining are known in art. No unexpected results have been noted.

Applicants argue that the present invention irradiates polysaccharide in a solid state whereas, the De Ambrosi et al patent disclose material in a liquid state being

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irradiated. This argument is not persuasive since the De Ambrosi et al patent does teach irradiation of glucoaminoglycans in the solid state (see the abstract).

Applicants also argue that the dosages of irradiation in the De Ambrosi et al and Makuuchi et al patents covers a wider range of electron beams than the more limited range of electron beams disclosed in instant Claims 22-24. This argument is not persuasive since the electron beam range disclosed in the De Ambrosi et al and Makuuchi et al patents covers the range of electron beam disclosed in Claims 22-24. Proportions of ingredients (electron beams in the instant case), to impart patentability to an otherwise obvious chemical composition, must produce more than a mere difference in degree in the properties of the composition. *In re Fields* (CCPA 1962) 304 F2d 691, 134 USPQ 242. The proportions must be critical, i.e., they must produce a difference in kind rather than degree. *In re Touvay et al.* (CCPA 1958) 264 F2d 901, 121 USPQ 265; *In re Selmi et al.* (CCPA 1946) 156 F2d 96, 70 USPQ 197; *In re Waite* (CCPA 1948) 168 F2d 104, 77 USPQ 586. There is no indication in the instantly claimed process that the saccharide fractions obtained therein are new. The De Ambrosi et al patent discloses obtaining glucosaminoglycans having a molecular weight between 1000 and 35,000 Daltons (see abstract) and further discloses that the glucosaminoglycans may be selected as hyaluronic acid (see column 4, line 67) as disclosed in instant Claims 22-24.

Applicants added new Claim 37, which recites that the glucosaminoglycan fraction is a fraction comprising at least one of chondroitin sulfate D and chondroitin sulfate E and Applicants argue that the chondroitin sulfate D and chondroitin sulfate E are not disclosed in the cited references. This argument is not persuasive since the De Ambrosi et al patent does recite that the glucosaminoglycans thereof may be selected as chondroitin-4-sulphate and chondroitin-6-sulphate (see column 4, last paragraph). One of ordinary skill in this art having the Ambrosi et al patent before him and knowing the effectiveness of the irradiation of chondroitin-4-sulphate and chondroitin-6-sulphate to produce saccharides having lowered molecular weights would expect that the irradiation process would also be effective for chondroitin sulfate D and chondroitin

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sulfate E. Hence, newly added Claim 37 does not indicate patentable subject matter in view of the Ambrosi et al patent.

Accordingly, the rejection of Claims 1, 3-6, 22-24 and 37 under 35 U.S.C. 103(a) as being unpatentable over the Makuuchi et al patent in view of the De Ambrosi et al patent is maintained for the reasons of record.

Summary

6. All the pending claims are rejected.

Conclusion

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

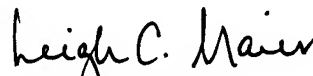
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-066127. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



E. White



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